

Civil No. 05-CV-0329 GKF-SAJ

Professor Harwood’s “biomarker” and Dr. Olsen’s “signature” theories are the lynchpins of the causation prong of Plaintiffs’ RCRA case. Plaintiffs assert that bacteria from poultry feces

are contaminating recreational waters in the IRW. Such a claim is usually supported by a traditional fate and transport study, documenting the fate and transport characteristics of the specific bacteria or chemicals of interest and following them through each step of the path they must follow in order to be the cause of specific contamination. *See, e.g., Sierra Club v. Strock*, 495 F. Supp. 2d 1188, 1229 n.154 (S.D. Fl. 2007); *Sierra Club v. El Paso Props.*, 2007 U.S. Dist. LEXIS 40434 at *14 & 14 n.7 (D. Colo. June 4, 2007). A proper study would account for the effect of the many factors that slow or kill bacteria including sunlight, oxygen, temperature, humidity, pH, salinity, desiccation, topography, vegetation, and predation, as well as account for alternate sources of the same bacteria. A proper study would also account for the other environmental sources of chemicals and how those chemicals move, dissipate, or concentrate under conditions in the specific environment. Daily Transcript (T.__) 770:23-773:6 (the daily transcript excerpts cited herein are attached as Exhibit 1). Finally, where, as here, the allegations rely on previously-unknown “signatures” or “markers,” a fate and transport study should also confirm that the new alleged “signatures” maintain a correlation to the pathogens whose presence they purport to signal as both the chemicals and bacteria allegedly move through varying vegetation, soils, and waters.

A. Plaintiffs’ Various Experts Have Admitted That Plaintiffs Did Not Conduct A Traditional Fate And Transport Study

During the argument on this motion following the close of their case, Plaintiffs told the Court that they have performed a fate and transport analysis. T. 1370:4-1371:10. To the contrary, Plaintiffs’ various experts have repeatedly admitted otherwise. As Dr. Harwood testified:

Q. You did not do a fate and transport analysis in this case?

A. Correct.

T. 764:10-12. *See also* T. 773:7-11; 775:15-775:18 (discussing fate and transport elements Professor Harwood did not study). Plaintiffs' other experts likewise admitted to performing no such study. *See* T. 338:13-15; 340:2-15 (Dr. Teaf did not perform a formal fate and transport study); T. 453:17-23 (Dr. Fisher was not asked to study bacterial fate and transport); Olsen Depo. 25:21-26; 318:21-319:6 (Dr. Olsen not asked to track movement of litter constituents from particular land-application sites to contamination) (Exhibit 2); T. 518:12-17 (Dr. Engel did not model bacterial fate and transport); T. 1252:15-21; 1296:1-1299:21 (Dr. Lawrence relied on the work of Drs. Teaf, Harwood, Olsen, and Fisher).

In lieu of a full fate and transport analysis, the case Plaintiffs presented to the Court relies entirely on Dr. Harwood's "biomarker" and Dr. Olsen's "signature" as shortcuts. Rather than demonstrate that indicator bacteria and pathogens from poultry feces survive the period of time litter sits on the poultry house floor, survive the physical and chemical stresses of land application, runoff, exposure to the elements, and soil filtration, survive in streams and groundwater, and ultimately reach recreational waters miles away, Plaintiffs assert that the presence of the "biomarker" or the "signature" in the environment proves that bacteria from poultry are reaching that location. Plaintiffs assert that these "signatures" therefore prove that any surrounding fecal indicator bacteria also come from poultry instead of from the multiple alternate and closer sources of those same bacteria, such as cattle and wildlife. This testimony is Plaintiffs' only causal link from poultry feces to the Watershed.

Plaintiffs bear the burden of proving by a preponderance of the evidence that this testimony is admissible. *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 n.4 (10th Cir. 2001). Rule 702 focuses not on the correctness of an expert's conclusions, but rather whether they derive from some recognizable and reliable scientific method. *Palmer v. ASARCO*

Inc., 510 F. Supp. 2d 519, 527 (N.D. Okla. 2007). Indeed, as the Supreme Court has made clear, “any and all scientific testimony or evidence admitted [must be] not only relevant, but reliable.” *Daubert*, 509 U.S. at 589. Therefore, “any step that renders the analysis unreliable . . . renders the expert’s testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.” *Mitchell v. Gencorp., Inc.*, 165 F.3d 778, 782 (10th Cir. 1999) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)). In determining whether expert testimony is reliable, district courts should examine, *inter alia*, whether a theory may and has been subjected to testing, whether it has been peer reviewed and published, its known or potential rate of error, and its level of acceptance in the scientific community. *Id.* at 780.

As discussed below, both Professor Harwood’s and Dr. Olsen’s testimony fail these standards. Their testimony was prepared entirely for litigation, following scripts provided by Plaintiffs’ lawyers. Moreover, both propose methodologies that are novel and untested, and which rely on flawed assumptions making them ultimately unreliable. For these reasons, the Court should exclude these two theories from these proceedings.

B. Dr. Olsen’s “Signature” Theory Should be Excluded as Unreliable.

Dr. Olsen utilized a shortcut in an effort to avoid the need to perform a full, time-consuming, and expensive fate and transport study of the extremely complex system of bacterial progression in the IRW. Dr. Olsen testifies that through the use of Principal Component Analysis (PCA), a statistical tool, he has identified a chemical and biological “signature” that is unique to poultry. T. 904:13-17. This work, undertaken exclusively for this litigation, is unreliable and should be excluded.

1. Dr. Olsen's Testimony Presents Litigation-Driven Theory, not Objective Science.

Scientific theories developed in the context of litigation are disfavored. *Daubert v. Merrill Dow Pharmaceuticals, Inc.* (“*Daubert II*”), 43 F.3d 1311, 1317-18 (9th Cir. 1995) (“[W]e may not ignore the fact that a scientist’s normal workplace is the lab or the field, not the courtroom or the lawyer’s office.”). This reflects the concern that retained expert testimony may “‘turn[] scientific analysis on its head. Instead of reasoning known facts to reach a conclusion, [a hired expert may] reason[] from an end result in order to hypothesize what needed to be known but what was not.’” *Mitchell*, 165 F.3d at 783 (quoting *Sorensen v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994)); *see also B.H. v. Gold Fields Mining Corp.*, 2007 U.S. Dist. LEXIS 4612 at *12 (N.D. Okla. Jan. 22, 2007) (“Defendants’ justifiably dispute plaintiffs’ attempt to create an after-the-fact justification that would bring [the expert witness’s] results within the range plaintiffs desire.”).

Dr. Olsen has served as Plaintiffs’ managing expert from the beginning of this case and has developed his alleged “signature” solely for this litigation. His alleged “signature” was not the product of preexisting work, but was created at Plaintiffs’ request. See T. 937:12-23 & Deft’s Ex. 275 (Exhibit 3). His firm, Camp Dresser & McKee, has been paid approximately \$6 million for his work. T. 934:12-20. That money has come not from the State of Oklahoma, but from Plaintiffs’ lawyers. T. 934:25-935:4. It is unclear whether Dr. Olsen actually performed all the work to which he testified, T. 980:8-15, but it is clear that, as with Professor Harwood, Dr. Olsen’s conclusions were foretold by Plaintiffs’ counsel before any samples were taken and any analysis was performed, T. 937:12-23 & Deft’s Ex. 275.

2. Dr. Olsen's Testimony is Novel, Untested, and not Peer Reviewed.

Because judicial determinations are best made on facts, not hypotheses, the courtroom is not the place for vetting new scientific theories. As the Supreme Court noted in *Daubert*, “there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.” 509 U.S. at 596-97. Under Rule 702, courts should rely on those theories that have *survived* scientific scrutiny, not those just beginning the process. Courts are therefore hesitant to rely on novel scientific theories. *See, e.g., Palmer*, 510 F. Supp. 2d at 530-31 (N.D. Okla. 2007) (rejecting as novel a theory that lead exposure causes attention deficit disorder); *Ingram v. Solkatronic Chem., Inc.*, 2006 U.S. Dist. LEXIS 38304, at **18-33 (N.D. Okla. Dec. 28, 2005) (rejecting expert’s “biotransformation” methodology that, while derived from existing methodologies, and despite the possibility that it might one day be an accepted theory, was unsupported in pre-existing literature); *B.H.*, 2007 U.S. Dist. LEXIS 4612 at **20-21 (excluding testimony of expert whose theory “exists only in his mind”).

Dr. Olsen has run and rerun his analysis. He has run it with as many as 35 different substances and bacteria as components of the analysis, and he has run it with as few as 19 components (along with various subjective choices of components in between these extremes). T. 958:13-15. He has run it with what he admits is bad data, and he has run it without bad data. T. 986:6-988:1. But none of these changes appears to have in any way affected his conclusion. T. 988:19-989:1. Whatever the number, type, and validity or invalidity of his inputs, Dr. Olsen has always seen a poultry litter “signature” that no other scientist has ever seen.

Dr. Olsen’s work is entirely novel. Despite decades of research into the poultry sciences, Plaintiffs’ experts are the first and only that have identified a poultry-specific “signature”:

Q. Dr. Olsen, out of all the scientists in the world who have studied water quality in areas where poultry production occurs, you're the only one, aren't you, sir, that holds the opinion that the list of parameters that we saw in your direct examination constitute a poultry signature?

A. Well, that poultry signature is specific to this basin, and I'm the only one besides other scientists in our company and one outside reviewer that's looked at this. So no other people outside the group or our scientific reviewer has seen this, so no one else has made that conclusion.

T. 960:9-21. *See also* Olsen Depo. 120:13-21. Despite decades of research by public and private researchers into the potential impact of poultry farming on water quality, Dr. Olsen alone has made this “unique” discovery. Olsen Depo. 121:3-122:2. Indeed, study of the IRW specifically over the past 20 years has identified no such signature. T. 961:12-962:12. And no one before now, outside Plaintiffs’ legal team, has ever reviewed Dr. Olsen’s PCA analysis. T. 959:22-960:8. It has been neither peer reviewed nor published. *Id.* As noted below, publication and peer review would likely result in the identification of significant and troublesome shortcomings in Dr. Olsen’s methodology.

First, Dr. Olsen’s methodology uses questionable sample selectivity. As Dr. Olsen admits, PCA results are a function of the data fed into the process. T. 944:2-6. Of the Plaintiffs’ 2,661 samples taken in this case, Dr. Olsen elected to include only 621 in his analysis. T. 944:10-16. He appears to have included principally those that contained some elements he identified as deriving from poultry litter. T. 971:11-972:23. The fact that over 75 percent of the environmental samples collected in this watershed did not even contain detectable amounts of the 25 parameters that Dr. Olsen claims constitute a unique poultry signature convincingly disproves Dr. Olsen's claim that his PCA analysis demonstrates that a unique chemical signature for poultry litter has been found throughout the watershed.

Second, Dr. Olsen’s component selection is itself questionable. While Dr. Olsen claims to have identified a signature unique to poultry litter, his PCA analysis omitted elements found in

poultry litter which, if he was correct, one would expect to find in the environment. T. 967:14-969:4. While Dr. Olsen proffered justifications for omitting elements such as nickel, chromium, lead, and molybdenum, it is explanations such as this that are ripe for challenge in the peer-review process. *Id.* Without peer review, the Court cannot know whether Dr. Olsen's decision to selectively exclude some elements from his analysis would be taken seriously in the scientific community. As noted above, Dr. Olsen has run his PCA analysis repeatedly, using as few as 19 components and as many as 35. T. 958:13-15. It is unclear why certain components made or did not make the cut. Such novel scientific issues must be sorted out in the scientific community before they can provide the basis of evidence in court.

Third, Dr. Olsen's approach also fails to account adequately for alternate sources of the many components of his analysis. Most, if not all, of the components comprised by his PCA analysis have one or many sources within the watershed apart from poultry. T. 962:22-964:22. Indeed, many of them occur naturally in the IRW. *See, e.g.*, T. 965:6-17 (limestone and calcium); T. 967:5-10 (nitrogen); T. 967:11-13 (potassium). Yet, significantly, while many of his PCA components derive from cattle, Dr. Olsen did not construct a "cattle signature" to ensure that he was not detecting cattle rather than poultry. T. 947:23-948:8; 949:23-950:7; 976:7-979:11. Nor does his methodology account for alternate sources of bacteria. T. 996:2-19. The existence of alternate sources is troublesome given the absence of any evidence that Dr. Olsen studied whether the fates of various components actually correlate in the environment. Huber Aff. ¶6. It is also troublesome given that PCA is an inappropriate tool to use to measure a system where components have multiple sources. T. 980:16-983:16; Brian L. Murphy & Robert D. Morrison, *Introduction to Environmental Forensics* 5 (2007). It is undisputed that numerous components of Dr. Olsen's PCA have multiple sources. T. 965:6-17; 967:5-13; 983:9-13.

The most devastating critique of Dr. Olsen's methodology is set out in Dr. Huber's affidavit. Among other methodological shortcomings, Dr. Huber notes Dr. Olsen's failure to develop the supporting documentation an experienced statistician would expect with a PCA, Huber Aff. ¶7, the improper use of averages rather than individual measurements, which artificially enhances perceived correlations, *id.* ¶9, the improper use of detection limits, *id.* ¶¶14-15, and the failure to classify properly separate data sources, *id.* ¶10. All of these serious flaws in Dr. Olsen's methods should be vetted through peer review before a court could accept these new ways of using PCA.

Like Polymerase Chain Reaction (PCR), PCA is also a tool applied in many different scientific and mathematical contexts. T. 873:12-874:16. This tool must be applied with care. For example, care must be taken to input reliable data from a single lab, or labs known to use identical methods. Murphy & Morrison at 464. Yet until the eve of the hearing, Dr. Olsen used corrupted data, and included inputs from multiple labs with no apparent quality control. T. 984:3-988:1. The mere fact that PCA is a recognized statistical tool sometimes employed in environmental investigations does not make Dr. Olsen's use of it either reasonable or reliable. Any tool, whether hammer or microscope, can be used incorrectly. The accuracy of PCA depends entirely on the quality and nature of the data fed into it and the proper use of the tool. T. 944:2-6. Moreover, extrapolating from PCA's results to a conclusion as to the source of constituents is entirely the subjective evaluation of the user, as Dr. Olsen admits. T. 957:5-959:16. It is clear that Dr. Olsen has wielded this tool in a novel and inaccurate manner. Huber Aff. ¶5 (discussing other methodological errors in Dr. Olsen's approach).

In the final analysis, Dr. Olsen's asserted poultry signature is the product of his own newly invented processes, not of any established scientific method. Dr. Olsen, not the PCA,

selected the input data; Dr. Olsen, not the PCA, decided how to manipulate it; and Dr. Olsen, not the PCA, labeled the output a “unique chemical signature” for poultry. This conclusion is untested, uncorroborated, unreviewed, and, ultimately, unsupported. The methodological flaws in his approach, along with the novelty of his proposed PCA parameters, render his testimony unreliable and therefore excludable.

C. Professor Harwood’s “Biomarker” Theory Should be Excluded as Unreliable

Professor Harwood testified to the identification of a poultry-associated “biomarker,” a genetic sequence which, according to her, exists only in a specific bacterium that is nearly unique to chickens and turkeys. The presence of this marker in the environment, she argues, indicates the presence of poultry-associated contamination.

1. Professor Harwood’s Testimony Reflects the Litigation-Driven Work of Others.

Professor Harwood was retained in 2004, but did not begin her substantive work on the case until the summer of 2005. T. 707:23-708:1. Before she began her substantive work, Plaintiffs’ lawyers and their managing expert, Dr. Olsen, determined what testimony they would elicit from Professor Harwood. T. 759:20-760:2; PI Ex. 275 (“Dr. Jodi Harwood will testify that the types and volume of bacteria in the environment is likely from land applied poultry waste and viruses associated with it.”). Professor Harwood had no input into or involvement with Plaintiffs’ sampling program, and much of sampling and water testing was complete before she began her work. Harwood Depo. 30:21-31:14; 197:21-23; 201:10-17; 321:16-25 (Exhibit 4). Professor Harwood based her testimony on reports and data received from Dr. Olsen. Harwood Depo. 30:21-31:14. Professor Harwood neither performed nor directed the laboratory work supporting her testimony. Rather, the work was carried out entirely by North Wind, Inc., a laboratory in Idaho. T. 708:10-21; Harwood Depo. 22:10-11, 22:3-5.

Far from following Professor Harwood's direction, North Wind followed a Scope of Work prepared initially by Dr. Olsen and his colleagues at CDM, at the direction of the Plaintiffs' lawyers. PI-Olsen00027912 ("Harwood . . . has agreed to assist as an expert. She has been sent the scope of work . . .") (Exhibit 5); PI-Harwood00000605-12 (Exhibit 6); Olsen Depo. 62:8-64:9; Harwood Depo. 198:19-24 (no involvement in drafting scope of work). Once North Wind completed its work, it provided a report to Dr. Harwood, which is the actual basis for her testimony. Harwood Depo. 225:11-17. This report, introduced into evidence by Defendants, documents work conceived and performed solely in the context of this litigation, and never reviewed by anyone outside Plaintiffs' legal team.

All Professor Harwood has done is testify to the results of the unreviewed work of others, based on a procedure she did not develop, using samples and measurements she did not take, all prepared at the direction of counsel. Like with Dr. Olsen, this work was undertaken solely as a part of this litigation. As such, Professor Harwood's testimony is of minimal value, and should be excluded.

2. Professor Harwood's Methodology is Unreliable because it is Novel, Unpublished, and Untested.

Professor Harwood's testimony regards a novel methodology of unknown accuracy, which has never been subjected to independent testing and which rests on several unsupported assumptions. As such, her testimony is highly unreliable and should be excluded.

a. The Plaintiffs' "Biomarker" Theory is Completely Novel.

The science of Microbial Source Tracking ("MST") is a young one, being at most 15 years old. T. 785:11-19; 787:2-12. In that time, literally dozens of approaches have been proposed, many of them subsequently rejected. Indeed, by her own testimony, Professor Harwood agreed that as late as 2003-2004, MST practitioners were relying on inaccurate

methodologies. T. 789:9-10; 793:20-794:7. And, as she wrote just last year, the MST field remains confusing and has yet to produce any methodology that can be relied upon consistently. T. 795:25-796:11. Responsible regulatory agencies agree with this candid assessment. Both the EPA and the USGS have cautioned against significant reliance on MST based on the current state of the science. T. 794:14-795:20; 796:13-17.

While the science of MST is young, the work underlying Professor Harwood's testimony is newborn. Plaintiffs' methodology employs newly-designed chemical primers to isolate a never-before seen DNA sequence, contained within a never-before identified bacterium. T. 733:1-5. Indeed, in one of Plaintiffs' experts' own words, "we would be justified in saying this stuff is not standard, given that we're dealing with a potential biomarker that has not previously been demonstrated and for which we had to design new primers." T. 803:2-11. As Professor Harwood herself candidly admitted to her colleagues, "[t]here is nothing standard about it." T. 804:8-10 & Exhibit 7. And, as Professor Harwood testified, "[t]here is no standard conventional method for specifically detecting poultry contamination in environmental waters." T. 728:12-17. *Accord* Myoda/Samadpour Aff. ¶24.

Professor Harwood asserted that Plaintiffs' approach is well established in the scientific community. T. 727:14-728:1. But what Professor Harwood in fact referred to were the tools used. For example, North Wind employed PCR. T. 727:14-16. PCR is a procedure for replicating strands of DNA with application in multiple scientific fields, not an MST methodology in and of itself. Rather, PCR is a tool, not unlike an electron microscope, which can be used in applying an MST methodology.¹ While Plaintiffs' tools are not new, their

¹ Plaintiffs assert that Defendants' Motions to Exclude take issue with conclusions rather than methodologies. Bench Brief at 4, 7. This is not the case. Professor Harwood's "conclusion" is that her "biomarker" indicates the presence of poultry-derived bacteria. Professor Harwood's

“poultry biomarker” methodology is entirely novel. Plaintiffs purport to have identified an entirely new species of *brevibacterium*, which is almost uniquely associated with two, and only two, birds . . . chickens and turkeys.

Professor Harwood also over-reached when she testified that Plaintiffs’ approach is employed in hospitals and criminal DNA testing. T. 728:2-11. Plaintiffs repeat this claim in their bench brief. Plaintiffs’ Bench Brief at 2-3 (citing sources). The approach used in these settings, molecular epidemiology, relies on an exact match between DNA samples from two known sources. Plaintiffs’ approach, by contrast, matches DNA extracted from a newly discovered and unknown bacterium against samples collected in the environment that may have come from one of a number of sources. Far from the one-to-one match required by molecular epidemiology, Plaintiffs’ approach leaves room for substantial subjectivity and error.

The fact is that the methodology to which Professor Harwood testified is entirely novel and unsupported in the scientific literature, and should therefore be excluded.

b. Plaintiffs’ “Biomarker” Theory is Unpublished, not Peer-Reviewed, and Highly Unreliable.

The reliability of any particular scientific testimony is best gauged through peer review and publication, which provide “a significant indication that [the work] is taken seriously by other scientists.” *Id.* Moreover, while peer review does not guarantee validity, it will “increase the likelihood that substantive flaws in methodology will be detected.” *Daubert*, 509 U.S. at

“methodology” determined *inter alia* whether to test alternate sources of the biomarker, whether to account for other sources of fecal indicator bacteria, whether to use statistically significant sample sizes, and so on. It is to these that Defendants’ direct their motion. That the logical result of these objections is to call Professor Harwood’s conclusion into question is merely a happy circumstance. Likewise for Dr. Olsen, Defendants’ object to his methodological decision to exclude selectively components of poultry litter, to exclude selectively certain samples, and to otherwise manipulate his data to reach his desired goal. This motion is not directed to his “conclusion” that the signature he claims to have identified derives from poultry litter, but to his methodology.

593. See also *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985) (“[T]he examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine.”). Where a theory or methodology has not been tested and reviewed it should not be relied upon in litigation. *Truck Ins. Exch. v. Magnatek, Inc.*, 360 F.3d 1206, 1211-13 (10th Cir. 2004); *Gold Fields Mining Corp.*, 2007 U.S. Dist. LEXIS 4612, at *13.

On account of its novelty, Plaintiffs’ MST methodology has never been tested or confirmed by anyone outside of Plaintiffs’ legal team. T. 743:2-7; 801:11-12. As noted, North Wind prepared a report for Professor Harwood. That report has never been published or subjected to peer review. As such, it has never faced the exacting scrutiny of impartial scientific eyes. T. 824:13-825:2. Defendants respectfully suggest that were this theory subjected to rigorous independent review, impartial observers would identify a number of substantial and worrisome irregularities.

First, and most importantly, Professor Harwood’s asserted “biomarker” is insufficiently specific. As Professor Harwood herself put it, host specificity is the “holy grail” of MST. T. 810:11-14. In this case, Plaintiffs ask the Court to take a leap of faith and forego a full fate and transport study on the basis that the “biomarker” is specific to poultry and therefore indicates other poultry-related bacteria. But Plaintiffs’ own evidence demonstrates that the same genetic sequence appears in bacteria carried by 100 percent of the bird species that Plaintiffs tested. T. 813:20-23. (Plaintiffs’ testing originally identified the same marker in cattle, but that is explained away as the result of contamination, T. 813:20-24, which is separately worrisome). Beyond this, Plaintiffs have no idea what other creatures carry this bacterium because their methodology did not call for them to be tested. T. 815:1-816:2. Most significantly, despite

being four-for-four at finding the bacterium in birds, Plaintiffs did not test a single other one of the dozens of species of birds and waterfowl that inhabit the IRW. T. 835:1-11.

Second, Plaintiffs' methodology did not call for statistically significant sample sizes. In order to conclude that Plaintiffs' testing of goose, duck, swine, cattle, and human feces produced a result that accurately reflects that source generally, the sample size should have been sufficiently large to accurately categorize that source. Professor Harwood agrees that a non-statistically significant sample size cannot be attributed to the whole. T. 828:4-9. But Plaintiffs offered no testimony documenting the statistical significance of its sample sizes, nor may the Court have any confidence that 24 composite cattle, 2 swine, 10 ducks, 10 goose, and 6 human samples accurately represent their source populations. Reliance on statistically insignificant sample sizes prove nothing about animals beyond those tested. Therefore, it cannot be said with any degree of certainty that cattle, swine, and humans do not carry this bacterium, or how many species of birds carry it.

Third, Plaintiffs' methodology inappropriately failed to test additional animals for presence of the "biomarker." Professor Harwood explained that Plaintiffs targeted those animals that contribute the most feces to the watershed. T. 816:4-16. This smacks of *post hoc* rationalization given that Plaintiffs made no effort to quantify other animals in the IRW, or their fecal contributions, in the first place. T. 782:1-785:7. It assumes, moreover, that the "biomarker"-carrying bacterium will appear in few species at most. But given that the Plaintiffs found this sequence in every single type of bird they tested, T. 835:6-11, this assumption is unwarranted. If the gene sequence does appear in bacteria carried by birds generally, then the combined fecal contributions of other creatures in the IRW are highly relevant. Second, Plaintiffs' methodology relies exclusively on quantity and ignores proximity. The bulk of

poultry litter is applied on fields a considerable distance from recreational waters, and its use is subject to State regulations prescribing set-backs and other limitations that curtail its ability to affect groundwater and surface water. Jaffe Aff. ¶¶10-12; Andrews Aff. ¶10; Myoda/Samadpour Aff. ¶13. Geese, ducks, and other animals, by contrast, deposit fecal matter directly into the very recreational waters at issue in this case. Yet, when asked whether fecal bacteria would have a better chance of entering the water if it was deposited “ten yards away” from a water body instead of on dry land two miles away, Professor Harwood replied that “[w]e really don’t usually split hairs that much. We’re looking at a big picture.” T. 830:14-831:4. In view of the many fate and transport challenges facing a bacterium traveling from a poultry house to recreational waters, this is hardly hair-splitting, and Plaintiffs’ methodology is flawed in assuming otherwise. *Accord* Harwood Depo. 170:25-171:14 (agreeing that proximate bacterial source would have a greater impact than a distant source).

Fourth, Plaintiffs have not proved that the “biomarker” bears any correlation to fecal indicator bacteria. Plaintiffs’ theory, as noted, is that the presence of the biomarker “proves” that surrounding fecal indicator bacteria also derive from poultry rather than from any of the many other, more proximate, sources of those same bacteria. But that assumption can hold only if the bacterium that contains the biomarker shares the same fate and transport characteristics as fecal indicator bacteria from poultry, such that the two will travel together. But Plaintiffs have not studied the fate and transport characteristics of their newly-discovered bacterium. T. 807:24-809:16. The only testimony supporting any correlation is Professor Harwood’s assertion that the bacterium correlates to *enterococci*. T. 752:9-753:16. But Professor Harwood measured this correlation in surface water, which contains *enterococci* from many different sources, not just poultry, which confounds any attempt to measure correlation. Whether a correlation exists must

be measured as an initial matter in the poultry litter, which (presumably) contains bacteria from only the single source of interest. And there, as Drs. Myoda and Samadpour explained, Plaintiffs' testing demonstrates that there is no correlation between the biomarker-carrying bacterium and *enterococci*, *E. coli*, or *fecal coliforms*. Myoda/Samadpour Aff. ¶28 & Ex. 3. Without this correlation, the presence of the biomarker proves nothing beyond its own presence.

Fifth, Plaintiffs' methodology makes no effort to account for alternate sources of bacteria. Many different species in the watershed carry fecal indicator bacteria as well as campylobacter and salmonella. T. 270:1-3; 780:20-781:25. The presence of these multiple sources confounds the ability of any indicator to link the presence of any of these to any particular source. Myoda Aff. ¶30. Even if Plaintiffs were correct that the presence of the biomarker suggests that surrounding fecal indicator bacteria derive from poultry, it would still not demonstrate that any pathogens present also derive from poultry.²

These are but a few areas of the North Wind report that independent peer review and other study might focus on, were the work published. These areas suggest a high degree of unreliability in Professor Harwood's testimony, making it unsuitable for reliance upon in litigation.

CONCLUSION

The methods created by Dr. Olsen and Professor Harwood are untested, unpublished, non-peer-reviewed, non-validated, and litigation-driven. Their work appears highly unreliable.

² This is particularly important in view of the failure of Plaintiffs' testing to find pathogens. T. 763:1-764:1; 858:1-4. Plaintiffs now assert that pathogens may be present but not culturable, T. 711:17-712:17. But "non-culturable" does not mean "non-detectable." A known bacterium, such as campylobacter, can be identified using means other than culturing. For example, the very method used by Plaintiffs, PCR, could be used to replicate and detect the presence of these pathogens. See, e.g., G. Inglis & L. Kalischuk, *Use of PCR for Direct Detection of Campylobacter Species in Bovine Feces*, 69 Appl. Environ. Microbio. 3435 (June 2003). The fact is that Plaintiffs simply elected not to do so.

Accordingly, the Court should exclude their testimony from further consideration in these proceedings.

Respectfully submitted,

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